Generic Learning Objectives in the Domain of Medical Device Physics

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Abstract

It has been suggested that the role of the biomedical physics-engineering educator in faculties of health sciences should focus primarily on the functioning and effective and safe use of medical devices. This is a wide-ranging role which has a legal basis particularly now that the definition of the term 'medical device' has been clarified in international legislation. The array, variety and complexity of medical devices is increasing rapidly with the swift advances in healthcare technology. However as medical device education is not keeping pace so are under-utilisation and the number of adverse clinical incidents arising from improper use. This paper describes a set of generic learning objectives which can be applied to the teaching of most medical devices. Such generic learning objectives are essential to ensure a consistent and coherent approach across the curricula of the various healthcare professions and to the development of international curricula as required by, for example the Bologna process in Europe. The application of this generic approach to the subsequent setting up of profession-specific learning objectives will be briefly illustrated in the area of medical imaging device physics education for radiographers.

Introduction

As medical devices play an increasingly significant role in healthcare it has been suggested that biomedical physics-engineering (BMPE) educators in faculties of health sciences should focus their efforts on the effective and safe use of medical devices [1, 2]

1 Legal definition of a medical device

The term 'medical device' is defined in the Medical Devices Directive 93/42/EEC. Two further directives 90/385/EEC and 98/79/EC deal respectively with active implantable medical devices (eg heart pacemakers) and with devices used for the *in vitro* diagnostic testing of specimens derived from the human body (eg reagents, calibrators, control materials, kits, instruments, apparatus etc).

2 Medical devices and the health professions

All health professions use medical devices to a lesser or greater extent. Owing to the various reports dealing with adverse incidents, national health regulatory agencies are pressing for standards of proficiency and adequate training in the use of these devices [3]. This will have a direct impact on the curricula of the healthcare professions.

3 The Bologna process

Concurrently and as a result of the Bologna Declaration the various healthcare professions are also involved in trans-European curriculum development. The Tuning Educational Structures in Europe project aims at points of convergence of competencies and learning outcomes to be achieved in programmes of study within the European Higher Education Area [4, 5].

4 Need for generic learning objectives in medical device education

Owing to the increased importance of multi-professional teams in modern healthcare it is highly desirable that the different professions use a common language and have similar attitudes towards the use of medical devices. This would help reduce communication errors which may lead to fatal consequences for the patient. The existing trans-European curriculum development networks are however highly profession specific. There is therefore a danger that as the different professions design their curricula independently of each other, medical device learning outcomes will be couched using different concepts and terminology. This can be exacerbated by the fact that different professions use different devices and also as a result of the fact that the particular devices that would be included in say cycle one (Bachelor) level for a particular profession might vary from one country to the other. In addition to this the number and type of medical devices are also changing rapidly with the swift developments in technology. All this points to a need for *generic* outcomes which are device and profession independent and which circumvent

the perennial curriculum development problems of future coverage (trying to predict what students may need to know in the future) and obsolescence. At the same time the outcomes must be robust enough to ensure effective learning. *Hence outcomes must be expressed in a way which permits flexible curriculum development yet be structured enough to guide teaching in a systematic way.*

5 Generic learning objectives for medical device physics

The aim of medical device physics teaching should be to ensure that by the end of the programme the student would have *the ability to use those medical devices utilised in a particular profession effectively whilst minimising risk to patient, self and colleagues.* This competency can be expressed in terms of learning outcomes (as advised in *Tuning* documentation) as follows.

For *each* device included in the curriculum of a particular profession the student would be able to:

- Describe the properties and/or function of the human tissues, systems, fluids, organs etc which the medical device seeks to measure, correct, replace etcState the specific diagnostic, therapeutic etc outcomes expected when using the deviceExplain the physics principles underpinning the functioning of the device and the device use protocols Describe the structure of specific commercially available devices including user option settings and controls
- Identify possible health hazards (eg mechanical, electrical, radiation) to patient, self and colleaguesDescribe device performance indicators which are directly related to device effectiveness or safety at a level appropriate for users Explain device and use protocol design variables which impact effectiveness or safety at a level appropriate for users
- Demonstrates a level of capability in the use of the device that ensures the required level of effectiveness whilst minimising risk to patient, self and colleagues.
- Explains limitations of the device and contraindications for use
- Describes the effect on effectiveness and risk arising from device malfunction or inappropriate user protocol and any artifacts arising from theseDemonstrates timely device malfunction recognition and local procedures for reporting such faults
- Demonstrates skill in preventive maintenance and quality control including calibration of the device appropriate for users Demonstrates an awareness that a device should be checked before use and in the case of re-usable devices left in a condition for subsequent use
- Demonstrates adherence to International, European, National and local legislation and/or regulations regarding the use of the device.Demonstrates ability in evaluating a device at a level appropriate for usersDescribes briefly alternative devices and future developments of the device

6 Application to radiography education

Radiography is a highly device intensive profession. The above generic outcomes are applicable to all the imaging modalities currently in use ranging from the relatively simple projection x-ray imaging to complex MRI systems. The outcomes are also suitable for emerging imaging technologies like hybrid PET-CT systems. ‘Effectively‘ here would refer to the production of images of sufficiently high diagnostic efficacy whilst ‘risk’ refers to health hazards such as carcinogenesis in the case of x-rays and biomagnetic hazards in MRI.

Discussion and Conclusions

Most of the above learning outcomes are inherent to physics curricula as they are considered routine practices within the physics community. However owing to the low level or even complete absence of a physics component in healthcare curricula many health care professionals do not have the correct scientific approach to the use of devices. This explains why often medical device incidents are the result of user error. The principal role of the medical physics educator in faculties of health sciences should be to act as a role model with respect to the scientific approach to the use of medical devices.

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